

the applicant did not act with due diligence during the applicable regulatory review period; or

(3) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence so that, even if the petition were granted, the petition would not affect the maximum patent term extension which the applicant is entitled to under 35 U.S.C. 156.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

§ 124.33 Standard of due diligence.

(a) In determining the due diligence of an applicant, APHIS will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. APHIS will take into consideration all relevant factors, such as the amount of time between the approval of an experimental use permit and licensure of the veterinary biological product.

(b) For purposes of this Part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearing

§ 124.40 Request for hearing.

(a) Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination by APHIS in accordance with § 124.32, that APHIS conduct an informal hearing on the due diligence determination.

(b) The request for a hearing must:

(1) Be in writing;

(2) Contain the docket number of the FEDERAL REGISTER notice of APHIS's regulatory review period determination;

(3) Be delivered to the Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010—8197.

(4) Contain a full statement of facts upon which the request for hearing is based;

(5) Contain the name, the address, and the principal place of business of the person requesting the hearing; and

(6) Contain a certification that the person requesting the hearing has served a true and complete copy of the request upon the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail (return receipt requested) or by personal service.

(c) The request must state whether the requesting party seeks a hearing not later than 30 days after the date APHIS receives the request, or, at the request of the person making the request, not later than 60 days after such date.

[58 FR 11369, Feb. 25, 1993, as amended at 59 FR 67617, Dec. 30, 1994; 64 FR 43045, Aug. 9, 1999]

§ 124.41 Notice of hearing.

No later than ten days before the hearing, APHIS will notify the requesting party, the applicant, the petitioner, and any other interested person of the date, time, and location of the hearing.

§ 124.42 Hearing procedure.

(a) The presiding officer shall be appointed by the Administrator of APHIS from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(b) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(c) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered

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at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and any general summary of the information which will be presented at the hearing in support of such action.

(d) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral and written information relevant to such action.

(e) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(f) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing

shall be included in the presiding officer's report of the hearing.

(g) The due diligence hearing will be conducted in accordance with rules of practice adopted for the proceeding. APHIS will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing. The standard of due diligence set forth in §124.33 will apply at the hearing. The party requesting the due diligence hearing will have the burden of proof at the hearing.

§ 124.43 Administrative decision.

Within 30 days after completion of the due diligence hearing, the Under Secretary for Marketing and Regulatory Programs, taking into consideration the recommendation of the Administrator, will affirm or revise the determination made under §124.32. APHIS will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and the requesting party, the applicant, and the petitioner.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]